Supreme Court, U.S.
FILED
JAN 15 1999
CLERK

No. 98-377

In The

Supreme Court of the United States

October Term, 1998

Q. TODD DICKINSON,
Acting Commissioner of
Patents and Trademarks,

Petitioner,

v.

MARY E. ZURKO et al.,

Respondents.

On Writ Of Certiorari To The
United States Court Of Appeals
For The Federal Circuit

BRIEF FOR AMICUS CURIAE BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF RESPONDENTS

BAKER & BOTTS, L.L.P.

RODGER L. TATE
THE WARNER
1299 Pennsylvania
Avenue, N.W.
Washington, D.C. 20004-2400
(202) 639-7700

SCOTT F. PARTRIDGE
Counsel of Record
One Shell Plaza
910 Louisiana
Houston, Texas 77002-4995
(713) 229-1234

BOB E. SHANNON
SCOTT K. FIELD
1600 San Jacinto Center
98 San Jacinto Blvd.
Austin, Texas 78701-4039
(512) 322-2500

Attorneys for Amicus Curiae

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

BEST AVAILABLE COPY

TABLE OF CONTENTS

Page

INTEREST OF AMICUS 1

BACKGROUND 3

SUMMARY OF ARGUMENT..... 4

ARGUMENT 5

I. A Change from the "Clearly Erroneous" Standard of Review to the APA Standard Would Lead to a Lack of Uniformity in Patent Law..... 5

II. The Commissioner Asks the Court to Ignore Repeated Congressional Inaction With Regard to the Standard of Review 9

III. *Stare Decisis* Counsels Against a Change in Existing Law..... 12

IV. Even Assuming that the APA is Applicable, the Standards Set Forth Therein Establish Only the Minimum Standard to be Applied on Appeal... 13

CONCLUSION AND STATEMENT OF RELIEF SOUGHT..... 14

TABLE OF AUTHORITIES

Page

CASES

Apex Hosiery Co. v. Leader, 310 U.S. 469 (1940)..... 9

Conservolite, Inc. v. Widmayer, 21 F.3d 1098 (Fed. Cir. 1994) 6

Fregeau v. Mossinghoff, 776 F.2d 1034 (Fed. Cir. 1985)..... 6

Hoover Co. v. Coe, 325 U.S. 79 (1945) 5

In re Leuders, 111 F.3d 1569 (Fed. Cir. 1997).....3, 6, 9, 10, 11

In re Napier, 55 F.3d 610 (Fed. Cir. 1993) 3

In re Zurko, 111 F.3d 887 (Fed. Cir. 1997)..... 3

In re Zurko, 142 F.3d 1447 (Fed. Cir. 1998)..... 3

Morgan v. Daniels, 153 U.S. 120 (1894)..... 9

Newman v. Quigg, 681 F. Supp. 16 (D. D.C. 1988), *affd*, 877 F.2d 1575 (Fed. Cir. 1989)..... 6

Panduit Corp. v. All States Plastic Mfg. Co., 744 F.2d 1564 (Fed. Cir. 1984)..... 7

Payne v. Tennessee, 501 U.S. 808 (1991)..... 12

Planned Parenthood v. Casey, 505 U.S. 833 (1992) 12

Ranney v. Bridges, 188 F.2d 588 (C.C.P.A. 1951) 10

United States v. Rutherford, 442 U.S. 544 (1979)..... 9

STATUTES AND RULES

5 U.S.C. § 559.....13, 14

35 U.S.C. § 135(c) 10, 11

TABLE OF AUTHORITIES – Continued

Page

35 U.S.C. §§ 141, 145-46 5

FED. R. CIV. P. 52(a)..... 6

S. Doc. No. 8, 77th Cong., 1st Sess. at 4, note 2 (1941) 10

MISCELLANEOUS

ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT, 139 (1947) 13, 14

BRIEF FOR AMICUS CURIAE BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF RESPONDENTS

The Biotechnology Industry Organization ("BIO") files this amicus brief in the above-entitled and numbered cause, in which this Court granted certiorari on November 2, 1998.[1] BIO has consent of all parties to this action to file this amicus brief. The letters providing such consent accompany this brief.

INTEREST OF AMICUS

The matter before the Court, the standard of review in appeals from the decisions of the United States Patent and Trademark Office, raises fundamental questions affecting the uniformity of judgments in patent law. A strong patent system supported by uniform and predictable judicial outcomes is of profound importance to BIO.

BIO represents over 740 companies, academic institutions, state biotechnology centers and related organizations in 46 states and more than 20 nations, engaged in the development of products and services in the areas of agriculture, biomedicine, biopharmaceuticals, diagnostics, food, energy and environmental applications. BIO's members conduct research and development programs

---

[1] Counsel for a party to this action took no part in authoring this brief. In addition, no other person or entity, other than BIO and its members or counsel, contributed monetarily to the preparation or submission of this brief.

primarily directed to the discovery of innovative techniques and products to treat and diagnose diseases and disorders. To date, the biotechnology industry has produced over 50 drugs approved by the Food & Drug Administration ("FDA"); these drugs have been used to treat over 100 million people. The diseases that these drugs treat include AIDS, cancer, diabetes, multiple sclerosis, cystic fibrosis and many other serious maladies. For most of these diseases, no known treatment existed prior to the development of a biotechnology product.

In 1996, our member companies invested 7.9 billion dollars on research and development and on production facilities. The biotechnology industry as a whole invested at nine times the rate of the average of other United States companies. This investment is particularly remarkable when it is realized that, because of their recent inception, only about 5% of our industrial members earn a profit. The patent system plays a fundamental role, therefore, in determining the expected future value of biotechnology products now being developed by our members.

A patent system that rewards innovation is essential for all innovators who seek protection for their discoveries. The biotechnology industry is a relatively nascent industry, with the number of beneficial new products in the research and development stage far outnumbering the actual products which have been placed in commerce. In our industry, a lead time of 10 years from initiation of product development to approval for commercialization by the FDA is typical. At this stage in the development of our emerging industry, patents represent a critically important and tangible benchmark which investors look

to for assurance that their investments in the new products of the future will be adequately protected. Thus, inventors from our industry have a special interest in this issue because incentives to invest in future research and development will be directly influenced by the Court's decision. Accordingly, BIO has a strong interest in ensuring that our nation's patent system provides uniform and predictable judicial outcomes.

BACKGROUND

In the present case, the United States Court of Appeals for the Federal Circuit reversed the decision of the Board of Patent Appeals and Interferences ("the Board") sustaining the Patent office examiner's rejection of Zurko's patent. *In re Zurko*, 111 F.3d 887 (Fed. Cir. 1997). The Commissioner of Patents and Trademarks ("Commissioner") moved for an en banc rehearing of the standard of review issue, which was granted. Upon rehearing, the Federal Circuit, sitting en banc, affirmed the earlier panel opinion. *In re Zurko*, 142 F.3d 1447 (Fed. Cir. 1998). The Commissioner now asks this Court to hold that the more deferential standard of review contained in the Administrative Procedure Act (APA) applies to review of patent decisions, rather than the "clearly erroneous" standard of review employed for over a century.

The Commissioner first made this belated request in 1993, nearly fifty years after the APA was enacted in 1946. *See In re Napier*, 55 F.3d 610 (Fed. Cir. 1993). The Commissioner repeated this request in *In re Leuders*, 111 F.3d 1569 (Fed. Cir. 1997). The Commissioner now invites the Court

to overrule over a century of precedent applying the proper standard of review and, in the process, to act where Congress has chosen not to. The Amicus submits this brief requesting that the Court not accept the Commissioner's invitation.

SUMMARY OF ARGUMENT

This United States Court of Appeals for the Federal Circuit was created for the primary purpose of achieving uniformity in patent law. If the Court accepts the Commissioner's invitation to change the standard of review in patent appeals to the more deferential APA standard, however, the Court will create a risk of inconsistent judgments that presently does not exist. The creation of potential inconsistency in the judgments of a court devised to achieve uniformity makes no logical sense. Instead of changing the standard of review on its own, this Court should defer to Congress to take any such action.

Such action, however, is admittedly unlikely. Congress has made changes in the patent system numerous times, but has not changed the standard of review applicable to patent appeals. Even after the enactment of the APA in 1946, courts continued to apply the clearly erroneous standard. Six years later, Congress made sweeping changes to the patent laws. Yet, even given this opportunity to reconcile what the Commissioner now claims is a conflict between the APA and the clearly erroneous standard, Congress took no action. In fact, Congress has

never taken action in this regard. This inaction demonstrates Congress' approval of the clearly erroneous standard as the applicable standard in patent appeals.

Moreover, this Court should not abandon over a century of legal precedent. The Commissioner has not pointed to a compelling reason for turning a consistent system of appeals on its head. In the absence of such a reason, this Court should not do so.

Finally, even assuming the APA applies to patent appeals, the APA's plain language makes clear that courts may apply a heightened standard of review. Section 559 makes clear that the APA does not limit additional requirements "otherwise recognized by law." The clearly erroneous standard is well-recognized in the law. Thus, the standards set forth in the APA are only minimum standards that do not preclude the imposition of less deferential standards of review by the courts, such as the clearly erroneous standard.

ARGUMENT

I. A Change from the "Clearly Erroneous" Standard of Review to the APA Standard Would Lead to a Lack of Uniformity in Patent Law.

As this Court has made clear, a patent applicant dissatisfied with the decision of the Board of Patent Appeals and Interferences has two avenues of relief: an appeal to the Federal Circuit or an appeal to district court. *Hoover Co. v. Coe*, 325 U.S. 79, 81-83 (1945); *see* 35 U.S.C. §§ 141, 145-46. Under either avenue of appeal, the

standard of review is the same – the decision of the Board is presumptively correct and is reviewed for "clear error." *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1100 (Fed. Cir. 1994); *Fregeau v. Mossinghoff*, 776 F.2d 1034, 1038 (Fed. Cir. 1985); *Newman v. Quigg*, 681 F. Supp. 16, 22 (D. D.C. 1988), *aff'd*, 877 F.2d 1575 (Fed. Cir. 1989).

If the Court accepts the Commissioner's invitation to change this well-established standard, it will create a risk of incongruous judgments. For example, the Federal Circuit could be presented with review of two rulings on the same patent, one on an appeal from the Board's decision under Section 306 of Title 35, after a re-examination precipitated by one district court, the other on an appeal from another district court. If the Court were to adopt the standard of review for Board decisions urged upon it, the Federal Circuit would be compelled to review district court findings under a heightened, clearly erroneous standard, *see* FED. R. CIV. P. 52(a), while giving more deference to the Board's findings on the same patent. Conceivably, the result would be that, under identical circumstances, the same patent could be held both valid and invalid. The Federal Circuit has recognized this possibility. *In re Leuders*, 111 F.3d 1569, 1577 (Fed. Cir. 1997).

The Federal Circuit has also rightly recognized that a difference in result depending on the appellate route taken makes no logical sense. *Fregeau*, 776 F.2d at 1038. "Moreover, a difference in result in this court is not logically justifiable, if the evidentiary record before the district court is the same as that before the board, simply because of the review route chosen." *Id.*

Differences in result based on the appellate route taken would fly in the face of Congress' intent in creating the Federal Circuit. In *Panduit Corp. v. All States Plastic Mfg. Co.*, 744 F.2d 1564, 1573-74 (Fed. Cir. 1984), the court quoted at length the Congressional intent underlying the Federal Courts Improvement Act of 1982, which created the Federal Circuit, noting the purpose of the Act was to provide:

> [A] forum that will increase doctrinal stability in the field of patent law. Based on the evidence it had compiled, the Hruska Commission singled out patent law as an area in which the application of the law to the facts of a case often produces different outcomes in different courtrooms in substantially similar cases. Furthermore, in a Commission survey of practitioners, the patent bar indicated that uncertainty created by the lack of national law precedent was a significant problem.
>
> * * *
>
> The creation of the Court of Appeals for the Federal Circuit will produce desirable uniformity in this area of the law.

Id. at 1574 (quoting S. Rep. 97-275, 97th Cong., 1st Sess. 5, *reprinted in* 1982 U.S. Code Cong. & Ad. News 11, 15). The stated purpose from the House of Representatives was quite similar to that of the Senate: " '[T]he central purpose [of the FCIA] is to reduce the widespread lack of uniformity and uncertainty of legal doctrine that exist in

the administration of patent law.' " *Id.* (quoting H.R. Rep. 97-312, 97th Cong., 1st Sess. 23).[2]

The Federal Circuit, after reciting this intent, noted the obvious – the primary objective of Congress in creating the Federal Circuit was to achieve uniformity and to reduce uncertainty in the area of patent law. *Id.* The court, in fact, viewed this Congressional intent as its "mandate." *Id.* The court went on to conclude that

> [t]he fundamental underpinning for uniformity was Congress' abhorrence of conflicts and confusion in the judicial system. That was the underlying motivation for the creation of the court, and it must remain the spirit and guiding principle of this court.

Id.

The Commissioner now calls on this Court to vitiate the Federal Circuit's self-described "spirit and guiding principle" by creating a scheme that Congress did not intend, a scheme that creates a potential for lack of uniformity that, at the present time, does not exist. The Commissioner has presented the Court with no compelling reason to contravene the purpose behind the Federal Circuit's creation. Congress had the opportunity to change the standard of review for patent appeals when it created the Federal Circuit; it chose not to do so. It should now be left for Congress to take action to change the applicable standard of review if it wishes to do so. Any other result would run afoul of Congress' intent and the

---

[2] The legislative history behind the creation of the Federal Circuit is set forth in detail in the opinion below.

purpose for which the Federal Circuit was created – uniformity.

II. The Commissioner Asks the Court to Ignore Repeated Congressional Inaction With Regard to the Standard of Review.

For over a century, the "clearly erroneous" standard, or an analogous standard of review, has been applied to appeals of patent cases. *See Morgan v. Daniels*, 153 U.S. 120, 129 (1894) ("It is enough to say that the testimony as a whole is not of a character or sufficient to produce clear conviction that the Patent Office made a mistake."). Several times within this consistent history of appellate review, Congress has made significant changes to the patent system. At no time in this repeated consideration of the patent system has Congress seen fit to address or change the standard of appellate review employed by the courts of appeals. *In re Leuders*, 111 F.3d 1569, 1575 (Fed. Cir. 1997).

This Court has recognized that when Congress is aware of a statutory construction and yet has not sought to alter that interpretation even though it has amended the statute in other respects, Congress' silence accurately reflects legislative intent. *United States v. Rutherford*, 442 U.S. 544, 554 n.10 (1979); *Apex Hosiery Co. v. Leader*, 310 U.S. 469, 487-89 (1940). As demonstrated below, Congress has been aware of the standard of appellate review in patent cases for a long time. Despite its awareness and many opportunities to change the patent statutes in this regard, Congress has taken no action to change the long-accepted standard of review.

Even when enacting the APA, Congress did not alter the standard of review consistently applied to patent

cases for over fifty years. Indeed, the Report of the Committee on Administrative Procedure, specifically stated that:

> Staff reports were completed in connection with all the agencies [herein listed] except the following which are affected by special circumstances: . . . Patent Office, Department of Commerce (the highly specialized character of the Patent Office and the insufficiency of the Committee's staff led first to postponement and then to abandonment of plans to study this agency).

S. Doc. No. 8, 77th Cong., 1st Sess. at 4, note 2 (1941). It is evident from this language that the APA was seen as not affecting patent matters. Thereafter, appellate courts concluded likewise and continued to apply the clearly erroneous standard of review. *See, e.g., Ranney v. Bridges*, 188 F.2d 588, 596 (C.C.P.A. 1951).

Six years after the enactment of the APA, Congress made sweeping changes in patent law. In 1952, Congress codified the patent laws in Title 35 and repealed all prior patent statutes. *In re Leuders*, 111 F.3d at 1576. Yet, given this significant opportunity to reconcile what the Commissioner now claims is a potential conflict between the standard employed by appellate courts and the standard of review under the APA, Congress took no action. *Id.*

Ten years later, Congress again amended the patent laws by incorporating review under the APA into a particular subsection: "Any discretionary action of the Commissioner under this subsection shall be reviewable under section 10 of the Administrative Procedure Act." 35 U.S.C. § 135(c). The addition of this language in section

135(c) raises this question: Why would Congress have felt compelled to add this language to the patent laws if the APA already applied broadly under all patent review statutes? The clear answer is that it would not have done so. This 1962 amendment establishes that Congress did not consider the APA to be broadly applicable to patent law.

Finally, as noted previously, Congress addressed appellate review under the patent laws in 1982 when it created the Federal Circuit. Again, Congress did not take the opportunity to make the APA standard of review applicable to patent cases even though the primary focus of Congressional action at that time was appellate practice under the patent laws. *Leuders*, 111 F.3d at 1577.

More than fifty years have passed since the enactment of the APA. Neither before its enactment, nor in the fifty years since, has the APA standard been employed when reviewing decisions of the Board. Yet, the Commissioner now asks this Court to cast aside precedent and ignore common sense in arguing for the overturning of the clearly erroneous standard. The Commissioner's invitation might have been appropriate for Congress' consideration in the 1940s; today, however, the standard of review in patent cases is a firmly established lexicon of the Federal Circuit and represents a model of predictability and consistency for the patent bar. This Court should not take it upon itself to change a standard of review tacitly approved by Congress for many decades. Instead, this Court should continue to allow the use of the familiar and time-tested clearly erroneous standard until Congress instructs otherwise.

III. *Stare Decisis* Counsels Against a Change in Existing Law.

The Federal Circuit and its predecessors have applied the clearly erroneous standard of review for over a century. To abandon the wealth of precedent in support of this standard would run counter to the principle of *stare decisis* and would indicate an unnecessary departure from precedent. This Court has made clear its preference: "*Stare decisis* is the preferred course because it promotes the evenhanded, predictable, and consistent development of legal principles, fosters reliance on judicial decisions, and contributes to the actual and perceived integrity of the judicial process." *Payne v. Tennessee*, 501 U.S. 808, 827 (1991).

This Court has outlined four factors that should be weighed when a court is considering disregard of prior decisions:

(1) where the rule of law "has been found unworkable;"

(2) whether the rule could be removed without considerable prejudice to those who have relied on it;

(3) whether the existing rule is a doctrinal anachronism discounted by society; and

(4) whether the premises of the rule have changed to an extent that the rule is now irrelevant or unjustifiable.

Planned Parenthood v. Casey, 505 U.S. 833, 855 (1992).

As noted by the Federal Circuit below, these factors weigh in favor of maintaining the present standard. The

principle of *stare decisis* and the need for uniformity and stability militate against the abandonment of a well-established standard that has been applied successfully for over a century. The Commissioner has demonstrated no principled reason for such a departure at this time or any change of circumstances that makes the issue of substantial importance.

IV. Even Assuming that the APA is Applicable, the Standards Set Forth Therein Establish Only the Minimum Standard to be Applied on Appeal.

Even assuming that the APA should apply to review of patent decisions, the Commissioner is incorrect that the APA mandates a standard other than the clearly erroneous standard of review. To the contrary, the standards of review listed in section 706 of the APA constitute only minimum standards of review, not a ceiling. Nowhere in the APA is a court prohibited from applying a more strict, less deferential standard.

In fact, the APA expressly allows heightened standards of review: "[these] sections . . . do not limit or repeal additional requirements imposed by statute or *otherwise recognized by law.*" 5 U.S.C. § 559 (emphasis added). The plain language of this passage makes clear that section 706 cannot be interpreted as defining maximum standards to be imposed. The Attorney General's Manual on the APA further supports this view: "The first sentence of Section 12 [a reference to section 559] is intended simply to indicate that the act will be interpreted as supplementing Constitutional and legal requirements imposed by

existing law." ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT, 139 (1947).

As stated above, the clearly erroneous standard is "recognized by law" and has been applied to patent cases for more than a century. Thus, this slightly heightened standard can be applied under the plain language of section 559 of the APA.

CONCLUSION AND STATEMENT OF RELIEF SOUGHT

The Amicus, therefore, requests that this Court affirm the judgment of the Federal Circuit.

Respectfully submitted,

BAKER & BOTTS, L.L.P.

RODGER L. TATE
THE WARNER
1299 Pennsylvania Ave. NW
Washington, D.C. 20004-2400
Telephone: (202) 639-7700
Facsimile: (202) 639-7890

BOB E. SHANNON
SCOTT K. FIELD
1600 San Jacinto Center
98 San Jacinto Blvd.
Austin, Texas 78701-4039
Telephone: (512) 322-2500
Facsimile: (512) 322-2501

SCOTT F. PARTRIDGE
Counsel of Record
One Shell Plaza
910 Louisiana
Houston, Texas 77002-4995
Telephone: (713) 229-1234
Facsimile: (713) 229-1522

Attorneys for Amicus Curiae